



BANBURY CENTER REPORTS

Therapeutic use of ketamine for treating severe depression: Risks and potential

Banbury Center, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, USA
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Organizers:

Hakon Heimer, Cure Alliance for Mental Illness, Cold Spring Harbor, New York, USA

Rhonda Robinson Beale, Blue Cross of Idaho, Meridian, Idaho, USA

Jan Witkowski, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, USA

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BACKGROUND

Ketamine is purported to be the only truly new and effective therapy discovered for depression in the past 50 years. As Charney, Krystal and colleagues demonstrated two decades ago, people who are severely depressed and often suicidal, respond rapidly to the common anesthetic, reporting dramatic mood changes within minutes. The benefits can last for several weeks, giving other standard therapies the opportunity to take effect.

Despite this, ketamine is not widely available. This is, in part, because the patent for the formulation of ketamine in current use is long expired, reducing the incentive for industry to promote a new indication for depression. In addition, the current method of administration is intravenous; this means that the drug must be administered by specialist personnel in a medical office. And, indeed, a patchwork of individual physicians, clinics specializing in anesthesia for palliative care or neuropathic pain, and a few psychiatry clinics at major institutions, are offering treatment to people with depression.

The complexities in the use of ketamine for treatment of depression are many but perhaps can be encapsulated in the following question: **If ketamine is valuable for the treatment of depression, what can, and should, be done to make it more widely available in a safe and effective way?**

This Banbury meeting convened representatives from academia, government, private payers, and pharmaceutical companies, as well as patient advocates. The aims of the meeting were to examine the research and policy needed to evaluate the efficacy and safety of ketamine with the goal of facilitating the proper use of ketamine through FDA-approved pathways.

After extensive and lively discussions the participants generally felt that while more data from future clinical trials would be useful, the efficacy of ketamine in helping those with the most severe forms of depression justified exploring what steps can be taken now to provide it safely. The meeting agreed on three steps: (1) procurement of a formal statement from an acknowledged professional organization or organizations, providing a clear and concise overview of the state of the field; (2) formation of a registry of patients receiving ketamine for the treatment of mood disorders; (3) support for continued research.



MEETING SESSIONS

Session 1: Current Knowledge and Ongoing Research

Chairperson: Sanjay Mathew, Baylor College of Medicine, Houston, Texas, USA

Dennis Charney, Icahn School of Medicine, New York, New York, USA and Maurizio Fava, Massachusetts General Hospital, Boston, Massachusetts, USA

Ketamine in Depression: Clinical Trial Evidence

Gerard Sanacora, Yale University, New Haven, Connecticut, USA

Lessons from other proposed rapidly acting antidepressants - pharmacological specificity and non-specific clinical effects

Elliot Ehrich, Alkermes, plc, Waltham, Massachusetts, USA

Opioid Modulation as a Treatment of Major Depressive Disorder

Charles Nemeroff, University of Miami, Miami, Florida, USA

Meta-analysis of Ketamine and related compounds in Depression

Alan Schatzberg, Stanford University, Stanford, California, USA, and Mi Hillefors, National Institute of Mental Health, Bethesda, Maryland, USA

Where next for research?

Session 2: Current Clinical Practice and Challenges

Chairperson: Rhonda Robinson Beale, Blue Cross of Idaho, Meridian, Idaho, USA

Albert Dahan, Leiden University Medical Center, Leiden, The Netherlands

Ketamine pharmacokinetics and pharmacodynamics: Efficacy and toxicity

Glen Brooks, New York Ketamine Infusions, New York, New York, USA

Current Clinical Practice and Challenges

Steven Levine, Ketamine Treatment Centers, Princeton, New Jersey, USA

Five years of clinical experience with ketamine treatment for depression in an outpatient/private practice setting

Mark Frye, Mayo Clinic, Rochester, Minnesota, USA

Ketamine Clinics for Treatment Resistant Depression: Infrastructure and Clinical Development

Mason Turner, Kaiser Permanente, San Francisco, California, USA

The role of ketamine in long-term treatment of depression: Legal, regulatory and ethical considerations in the use of ketamine

Session 3: Stakeholder concerns

Chairperson: Anil Malhotra, North Shore-LIJ Health System, Glen Oaks, New York, USA

Maria Isaac, European Medicines Agency, London, United Kingdom

Dennis Hartman, Ketamine Advocacy Network, Seattle, Washington

Paul Summergrad, Tufts Medical Center, Boston, Massachusetts, USA

Rhonda Robinson Beale, Blue Cross of Idaho, Meridian, Idaho, USA

Ilse Wiechers, Department of Veterans Affairs, West Haven, Connecticut, USA

Session 4: Recommendations and Next Steps

Chairperson: Howard Goldman, University of Maryland, Potomac, Maryland, USA



MEETING PARTICIPANTS

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